

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

THIS PAGE BLANK (USPTO)

N/C



09/936505

The
Patent
Office

PCT/EP 00 / 01446

REC'D 28 MAR 2000

WIPO

PCT

INVESTOR IN PEOPLE

#5

EPO0/01446

EPO - DG 1

23. 02. 2000

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH
RULE 17.1(a) OR (b)

(86)

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

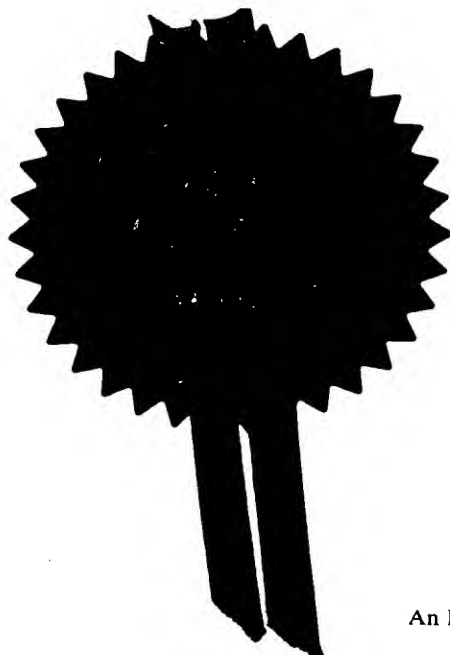
(4)

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.



Signed

Andrew Gersey

Dated 19 January 2000

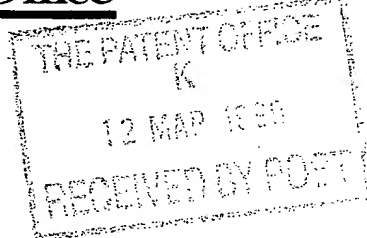
THIS PAGE BLANK (USPTO)

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
Newport
Gwent NP9 1RH



1. Your reference

CGP / PG3671

2. Patent application number

(The Patent Office will fill in this part)

9905568.3

3. Full name, address and postcode of the or of each applicant (underline all surnames)

172 MAR 1999
GLAXO GROUP LTD
GLAXO WELLCOME HOUSE
BERKELEY AVENUE
GREENFORD
MIDDLESEX UB6 0NN
UNITED KINGDOM

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

473587002
JF

4. Title of the invention

METERING VALVE

5. Name of your agent (if you have one)

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

DR CHRISTOPHER G PIKE
PIKE & CO.
3 KLONDYKE
MARLOW
BUCKS
SL7 2QQ

Patents ADP number (if you know it)

7593981001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number
(if you know it)

Date of filing
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing
(day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:

- a) any applicant named in part 3 is not an inventor, or
 - b) there is an inventor who is not named as an applicant, or
 - c) any named applicant is a corporate body.
- See note (d))

YES

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form 0

Description 15

Claim(s) 7

Abstract 1

Drawing(s) 8 & Y

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination (Patents Form 10/77)

Any other documents (please specify)

11. I/We request the grant of a patent on the basis of this application.

Signature

Date 11 MARCH 1999

DR C G PIKE - AGENT FOR THE APPLICANT

12. Name and daytime telephone number of person to contact in the United Kingdom

DR C G PIKE 01628 471869

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

- If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.
- Write your answers in capital letters using black ink or you may type them.
- If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.
- If you have answered 'Yes' Patents Form 7/77 will need to be filed.
- Once you have filled in the form you must remember to sign and date it.
- For details of the fee and ways to pay please contact the Patent Office.

Metering valve

This invention relates to a metering valve for an aerosol container. The valve is particularly suitable for use in the metered dispensing of medicament by way of an inhalation device.

It is known to dispense medicament in aerosol form from a metered dose inhalation device. Such devices commonly comprise a housing and supported therein, a container for the aerosol formulation. The container has a metering valve which generally is a slide or rotary valve. The slide or rotary valve comprises a valve stem which is movable against a restraining, generally frictional, force within a valve body from a dispensing position to a non-dispensing position.

In more detail, a slide valve typically comprises a valve body and within the valve body a sealing ring. A valve stem having a dispensing passage therein is frictionally received by the sealing ring. The valve stem is slidably movable within the sealing ring from a valve-closed position to a valve-open position in which the interior of the valve body is in communication with the dispensing passage. An illustrative slide valve is described in PCT application no. W096/28367.

Actuation of a slide valve involves the application of sufficient mechanical force to overcome the frictional force between the valve stem and the sealing ring.

In currently marketed inhalation devices the mechanical force required to actuate the slide valve is generally of the order of 20-40N. This force is often supplied by the patient manually depressing the container and valve body attached thereto relative to the housing and valve stem supported thereby. The movement of the valve body relative to the valve stem results in actuation of the valve and hence release of medicament.

With some current inhalation devices having a slide or rotary valve the valve stem tends to stick, pause, or drag during the actuation cycle with the result that the patient perceives a 'notchiness' as the valve stem is moved. This may be partly caused by medicament sedimenting or precipitating out of the aerosol

formulation and depositing on the internal valve components, the presence of medicament on the sliding interface increasing the frictional force between the valve stem and the frictional seal. Various solutions to the problem of valve notchiness have been suggested including the use of lubricant on the valve stem and the seal.

It may be understood that effective delivery of medicament to the patient using an inhalation device as described above is to an extent dependent on the patient's ability to co-ordinate the actuation of the device (e.g. firing of the aerosol) with the taking of a sufficiently strong inward breath. The required co-ordination can present difficulties to some patients, with the risk that these patients do not receive the appropriate dose of medicament. There have thus, been efforts to develop inhalation devices which do not rely on manual actuation by the patient, in particular those which are actuatable in response to the breath of a patient. These devices are often known as breath-actuatable devices.

Breath-actuatable devices typically comprise a source of stored energy which on release actuates the slide valve of the medicament container and hence release of medicament and a breath trigger which triggers the release of the stored energy in response to the breath of the patient. The stored energy source is required because the force required to actuate the slide valve (e.g. 20-40N as mentioned above) is too great to be suppliable by the patient's breath alone. Illustrative breath-actuatable devices are described in U.S. patent no. 5,655,523.

The applicants have now developed a metering valve which may be actuated without any need for a dispensing stem to be moved relative to a valve body. Since the new valve requires no relative movement of a valve stem to the valve body the problem of 'notchiness' associated with current slide valves is eliminated.

The newly developed metering valve is furthermore, operable by the application of significantly lower force than is required to operate a conventional metering valve having a slide or rotary valve. The force required can indeed, be so low that the valve is actuatable by the force of a patient's breath alone. The present

metering valve is thus, particularly suitable for use in breath-activated devices. Such devices can be much simpler than current breath-actuated devices because they do not necessarily require a source of stored energy.

5 According to the present invention there is provided a metering valve for an aerosol container comprising a valve body defining a metering chamber; said metering chamber having an inlet and an outlet, said inlet permitting flow of aerosol from said container to the metering chamber and said outlet permitting dispensing of aerosol from the metering chamber; the inlet having an inlet valve reversibly actuable from an open to a closed position; and the outlet having an outlet valve reversibly actuable from a dispensing to a non-dispensing position, wherein said outlet valve comprises a outlet valve seat and an outlet valve poppet in biasable contact therewith.

15 As used herein the term valve poppet means any element which is receivable by a valve seat to form a valve seal and which is movable from the valve seat to break the valve seal. The valve poppet can be of essentially any suitable shape.

20 Preferably, the metering valve forms a single integral unit which may conveniently be fitted onto known aerosol containers for use in the dispensing of medicament.

25 Preferably, the inlet valve comprises an inlet valve seat and an inlet valve poppet in biasable contact therewith.

Preferably, the valve additionally comprises an outlet valve mover for moving the outlet valve poppet out of contact with the outlet valve seat.

30 Preferably, the valve additionally comprises an inlet valve mover for moving the inlet valve poppet out of contact with the inlet valve seat.

Preferably, either or both of said inlet valve mover or said outlet valve mover is mechanically actuable. That is to say, actuable by application of mechanical

force either directly or through a mechanism capable of transferring mechanical force.

5 Preferably, either or both of the inlet valve mover or the outlet valve mover is electrically actuatable. That is to say actuatable by application of electrical current. More preferably, either or both of the inlet valve mover or the outlet valve mover comprises a multi-component strip which is deformable in response to electrical current flow. The multi-component strip typically comprises a plurality of layers of material, each material having a different coefficient of thermal expansion.

10 Preferred examples of multi-component strips include strips comprising multiple layers of different metals (e.g. bimetallic strips) and strips comprising at least one piezoelectric material.

15 Preferably, either or both of the inlet valve mover or the outlet valve mover is magnetically actuatable.

20 Preferably, either or both of the inlet valve mover or the outlet valve mover comprises magnetic material or material which is magnetically inductive, that is to say material into which magnetism can be induced. The material may be permanently or non-permanently magnetisable.

Preferably, either or both of the inlet valve mover or the outlet valve mover is pneumatically actuatable.

25 Preferably, either or both of the inlet valve mover or the outlet valve mover is hydraulically actuatable. More preferably, either or both of the inlet valve mover or the outlet valve mover comprises means, such as a fluid-filled bag or tube capable of transferring hydraulic force.

30 Preferably, the outlet valve poppet and/or the inlet valve poppet comprises an element in the form of a ball, a mushroom, a cone, a disc or a plug.

35 Preferably, the valve body additionally defines a sampling chamber and the inlet permits flow from the sampling chamber to the metering chamber.

According to another aspect of the present invention there is provided an aerosol container comprising a metering valve as described above.

5 In a preferred aspect the valve body of the metering valve is not movable relative to the container. Also, the metering valve contains no movable stem. This contrasts with current slide valves where actuation of the valve is achievable by relative movement of the aerosol container to the valve stem.

10 In one aspect, the aerosol container comprises a suspension of a medicament in a propellant. More preferably, the propellant is liquefied HFA134a, HFA-227 or carbon dioxide. More preferably, the medicament is selected from the group consisting of albuterol, salmeterol, fluticasone propionate, beclomethasone dipropionate, salts or solvates thereof and any mixtures thereof.

15 In another aspect, the aerosol container comprises a compressed gas, preferably compressed air.

20 According to a further aspect of the present invention there is provided an inhalation device for dispensing medicament to a patient comprising a housing; an aerosol container, locatable within said housing, said aerosol container comprising a metering valve as described above; and an outlet valve trigger for triggering the movement of the outlet valve poppet out of contact with the outlet valve seat.

25 When the aerosol container comprises an inlet poppet valve the inhalation device preferably also comprises an inlet valve trigger for triggering the movement of the inlet valve poppet out of contact with the inlet valve seat.

30 Preferably, either or both of said outlet valve trigger or said inlet valve trigger is triggerable in response to the breath of a patient.

Preferably, either or both of the outlet valve trigger or the inlet valve trigger communicates with a sensor which senses the breath of a patient.

In one aspect, the sensor comprises an breath-movable element which is movable in response to the breath of a patient. Preferably, the breath-movable element is selected from the group consisting of a vane, a sail, a piston and an impeller.

5

In another aspect, the sensor comprises a pressure sensor for sensing the pressure profile associated with the breath of a patient.

10

In a further aspect, the sensor comprises an airflow sensor for sensing the airflow profile associated with the breath of a patient.

In a further aspect, the sensor comprises a temperature sensor for sensing the temperature profile associated with the breath of a patient.

15

In a further aspect, the sensor comprises a moisture sensor for sensing the moisture profile associated with the breath of a patient.

20

In a further aspect, the sensor comprises a gas sensor for sensing the oxygen or carbon dioxide profile associated with the breath of a patient.

In a further aspect, the sensor comprises a piezoelectric element.

25

The outlet valve trigger and the inlet valve trigger may be independently triggerable or they may be triggerable in a coupled fashion.

30

Preferably, either or both of the outlet valve trigger or the inlet valve trigger is a mechanical trigger. In one aspect, the mechanical trigger comprises a lever mechanism. In another aspect, the mechanical trigger comprises a torque transfer mechanism.

35

Preferably, either or both of the outlet valve trigger or the inlet valve trigger comprises comprises a multi-component strip which is deformable in response to electrical current flow. The multi-component strip typically comprises a plurality of layers of material, each material having a different coefficient of thermal expansion. Preferred examples of multi-component strips include strips

comprising multiple layers of different metals (e.g. bimetallic strips) and strips comprising at least one piezoelectric material.

5 Preferably, either or both of the outlet valve trigger or the inlet valve trigger is a magnetic trigger.

10 In one aspect, the outlet valve trigger interacts magnetically with the outlet valve poppet and/or the inlet valve trigger interacts magnetically with the inlet valve poppet.

15 In another aspect, the outlet valve trigger interacts magnetically with a outlet shuttle contacting the outlet valve poppet and/ or the inlet valve trigger interacts magnetically with a inlet shuttle contacting the inlet valve poppet. Preferably, the outlet shuttle and/or inlet shuttle comprises magnetic material.

20 In a further aspect, the outlet shuttle comprises material which is magnetically inductive and the outlet valve trigger comprises an inductive element capable of inducing magnetism therein and/or the inlet shuttle comprises material which is magnetically inductive and the inlet valve trigger comprises an inductive element capable of inducing magnetism therein.

25 Preferably, either or both of the outlet valve trigger or the inlet valve trigger is a pneumatic trigger.

30 Preferably, either or both of the outlet valve trigger or the inlet valve trigger is a hydraulic trigger. More preferably, the hydraulic trigger comprises a fluid-filled bag or tube capable of transferring hydraulic force.

The invention will now be described further with reference to the accompanying drawing in which:

Figure 1 is a sectional view of a first metering valve in accord with the present invention;

Figure 2 is a sectional view of a second metering valve in accord with the present invention;

Figure 3 is a sectional view of a third metering valve in accord with the present invention;

Figure 4 is a sectional view of a fourth metering valve in accord with the present invention;

Figure 5a is a sectional view of a fifth metering valve in accord with the present invention;

Figure 5b is a sectional view of a detail of the valve of Figure 5a;

Figure 6 is a sectional view of a sixth metering valve in accord with the present invention;

Figure 7 is a plan view of the valve actuation mechanism of a seventh metering valve in accord with the present invention; and

Figures 8a to 8d show various forms of poppet valve suitable for use in accord with the invention.

Figure 1 shows an aerosol metering valve herein. The valve comprises a valve body 10 which defines a metering chamber 12 and a sampling chamber 14. The metering chamber 12 has an inlet 20 permitting flow of aerosol from the sampling chamber 14 which in turn receives aerosol from a container (not shown) and an outlet 30 permitting dispensing of aerosol from the metering chamber 12. The inlet 20 is provided with valve means comprising a valve seat 22 and a valve poppet in the form of a metal ball 24. The metal ball 24 is biased towards the valve seat 22 by the action of spring 26. The outlet 30 is also provided with valve means comprising a valve poppet in the form of a metal ball 34 held by a spring 36 in biased contact with a valve seat 32. The valve body 10 is within a housing 6 shaped such as to define a circular track 8 running upwardly in parallel with the exterior of the valve body 10. Within the

track 8 is contained a magnetic ring 40 which is movable up and down the track 8.

5 Actuation of the valve of Figure 1 is achievable by movement of the magnetic ring 40 which can magnetically interact with the metal ball valves 24,34 to dislodge them from their seats 22, 32. Movement of magnetic ring itself is for example, achievable by use of a second magnet (not shown). In a typical operation the inlet 20 valve will first be opened to allow metered flow of aerosol from the sampling chamber 14 into the metering chamber 12. The outlet 30
10 valve is then opened to allow for dispensing of the aerosol.

Figure 2 shows an aerosol metering valve herein. The valve comprises a valve body 110 which defines a metering chamber 112 and a sampling chamber 114. The metering chamber has an inlet 120 permitting flow of aerosol from the
15 sampling chamber 114 and an outlet 130 permitting dispensing of aerosol from the metering chamber 112. The inlet 120 is provided with valve means comprising a valve seat 122 and a valve poppet in the form of a resilient ball 124. The ball 124 is biased towards the valve seat 122 by the action of spring 126. The outlet 130 is also provided with valve means comprising a valve
20 poppet in the form of a ball 134 biased into contact with a valve seat 132 by action of spring 136. The valve body 110 is within housing 106 and the housing is provided with fixing screws 107, 109 for fixing the valve to an aerosol container (not shown). Movable magnetic rings 140, 142 contact the resilient balls 124, 134 of the inlet 120 and outlet 130 valves respectively. The magnetic
25 rings 140, 142 are in turn in magnetic communication with shuttle magnets 150 and 152.

30 Actuation of the metering valve of Figure 2 is achievable by movement of the magnetic rings 140, 142 to physically dislodge the resilient balls 124, 134 from their respective seats 122, 132. Movement of magnetic rings is achievable by movement of the shuttle magnets 150, 152. The shuttle magnets 150, 152 may, in turn be coupled to a mechanical trigger such as a lever mechanism (not shown). In a typical operation the inlet 120 valve will first be opened to allow metered flow of aerosol from the sampling chamber 114 into the metering

chamber 112. The outlet 130 valve is then opened to allow for dispensing of the aerosol.

Figure 3 shows an aerosol metering valve herein. The valve comprises a valve body 210 which defines a metering chamber 212. The metering chamber has an inlet 220 permitting flow of aerosol from a container (not shown) and an outlet 230 permitting dispensing of aerosol from the metering chamber 212. The inlet 220 is provided with valve means comprising a valve seat 222 and a valve poppet in the form of a resilient plastic ball 224. The ball 224 is biased towards the valve seat 222 by the action of spring 226. The outlet 230 is also provided with valve means comprising a valve poppet in the form of a resilient plastic ball 234 biased into contact with a valve seat 232 by action of spring 236. The valve body 210 is within a housing 206. The housing 206 shaped is such as to define two circular cavities 208, 209, each running upwardly in parallel with a portion of the exterior of the valve body 210 and respectively positioned around the inlet 220 and outlet 230 valves. First and second circular solenoid cores 240, 242 are movably located within the first and second circular cavities 208, 209 and respectively engage the inlet and outlet ball valves 224, 234. The circular solenoid cores 240, 242 are in turn, positioned for inductive communication with outer solenoid coil windings magnets 250 and 252. The solenoid coil windings 250, 252 are connected to an electrical power source.

Actuation of the metering valve of Figure 3 is achievable by movement of the circular solenoid cores 240, 242 to physically dislodge the resilient balls 224, 234 in an upward direction from their respective seats 222, 232. Movement of the circular solenoid cores 240, 242 is in turn achievable by the application of electrical current to the solenoid coil windings 250, 252. In a typical operation the inlet 220 valve will first be opened to allow metered flow of aerosol into the metering chamber 212. The outlet 230 valve is then opened to allow for dispensing of the aerosol.

Figure 4 shows an aerosol metering valve herein. The valve comprises a valve body 310 which defines a metering chamber 312 and a sampling chamber 314. The metering chamber has an inlet 320 permitting flow of aerosol from the sampling chamber 314 and an outlet 330 permitting dispensing of aerosol from

the metering chamber 312. The inlet 320 is provided with valve means comprising a valve seat 322 and a valve poppet in the form of a resilient ball 324. The ball 324 is biased towards the valve seat 322 by the action of spring 326. The outlet 330 is also provided with valve means comprising a valve poppet in the form of a resilient ball 334 biased into contact with a valve seat 332 by action of spring 336. Gripping arms 340, 342 grip the resilient balls 324, 334 of the inlet 320 and outlet 330 valves respectively. The gripping arms are formed from a bimetallic strip wherein each of the bimetallic components thereof has a different coefficient of thermal expansion. The gripping arms 340, 342 are connectable to an electrical power source.

Actuation of the metering valve of Figure 4 is achievable by movement of the gripping arms 340, 342 to physically dislodge the resilient balls 324, 334 from their respective seats 322, 332. Movement of the gripping arms 340, 342 is in turn achievable by the application of electrical current which causes deformation of the bimetallic strip from which the arms are formed. In a typical operation the inlet 320 valve will first be opened to allow metered flow of aerosol into the metering chamber 312. The outlet 330 valve is then opened to allow for dispensing of the aerosol.

Figure 5a shows an aerosol metering valve herein and Figure 5b shows a detail of this valve when the inlet valve is in the open position. The metering valve comprises a valve body 410 which defines a metering chamber 412 and a sampling chamber 414. The metering chamber has an inlet 420 permitting flow of aerosol from the sampling chamber 414 and an outlet 430 permitting dispensing of aerosol from the metering chamber 412. The inlet 420 is provided with valve means comprising a valve seat 422 and a valve poppet in the form of a resilient ball 424. The ball 424 is biased towards the valve seat 422 by the action of spring 426. The outlet 430 is also provided with valve means comprising a valve poppet in the form of a resilient ball 434 biased into contact with a valve seat 432 by action of spring 436. Shaped, flexible elastomer bags 440, 442 sit within and on both sides of access holes 416, 418 provided in the sampling chamber 414 and metering chamber 412 respectively. The elastomer bags 440, 442 contain fluid material. It may be seen that one portion of each of the elastomer bags 440, 442 contacts the resilient balls 424, 434 of the inlet

420 and outlet 430 valves respectively. It may also be seen that another portion of each of the elastomer bags 440, 442 contacts an impacting arm 450 which is pivoted at pivot 454. The impacting arm 450 is itself connected to handle 456 which may itself be attached to a breath-actuable vane (not shown).

5

Actuation of the metering valve of Figures 5a and 5b is achievable by impacting the flexible, fluid-filled elastomer bags 440, 442 to physically dislodge the resilient balls 424, 434 from their respective seats 422, 432. Impaction of the elastomer bags 440, 442 is in turn achievable by the impacting movement of the impacting arm 450. The bags 440, 442 are shaped such as to deform upon impact to allow for transfer of the energy of impaction through the fluid contents. The deformation of one of the bags 440 on being struck by the impacting arm 450 is shown in Figure 5b which also shows the dislodgement of the resilient ball 424 from its seat 422. In a typical operation the inlet 420 valve will first be opened to allow metered flow of aerosol into the metering chamber 412. The outlet 430 valve is then opened to allow for dispensing of the aerosol. It will be appreciated that the illustrated pivotal mounting 454 of the impacting arm 450 only allows for impaction of one of the elastomer bags 440, 442, and hence opening of only one of the inlet 420 or outlet 430 valves, at a time.

20

Figure 6 shows an aerosol metering valve herein. The valve comprises a valve body 510 which defines a metering chamber 512 and a sampling chamber 514. The metering chamber has an inlet 520 permitting flow of aerosol from the sampling chamber 514 and an outlet 530 permitting dispensing of aerosol from the metering chamber 512. The inlet 520 is provided with valve means comprising a valve seat 522 and a valve poppet in the form of a resilient ball 524. The ball 524 is biased towards the valve seat 522 by the action of spring 526. The outlet 530 is also provided with valve means comprising a valve poppet in the form of a ball 534 biased into contact with a valve seat 532 by action of spring 536. The valve body 510 is within a housing 506 and the housing is provided with fixing screws 507, 509 for fixing the valve to an aerosol container 503 (shown in part only). Shaped pins 540, 542 sit within and on both sides of access holes 516, 518 provided in the sampling chamber 514 and metering chamber 512 respectively. It may be seen that the tail end of each of the shaped pins 540, 542 contacts the resilient balls 524, 534 of the inlet 520

35

and outlet 530 valves respectively. It may also be seen that the head of each of the pins 540, 542 contacts an elastomer diaphragm 546, 548 which in turn contacts double-headed transfer pins 546, 548. The elastomer diaphragms 456, 548 and the transfer pins 550, 552 are mounted in side compartments of the valve body. The outer heads of the transfer pins 546, 548 are impactable by an impacting arm 560 which is pivoted at pivot 564. The impacting arm 560 is may itself connected to a breath-actuable vane (not shown).

Actuation of the metering valve of Figure 6 is achievable by movement of the shaped pins 540, 542 to physically dislodge the resilient balls 524, 534 from their respective seats 522, 532. Movement of the shaped pins 540, 542 is in turn achievable by impacting the elastomer diaphragms 546, 548 with their respective transfer pins 550, 552 following an impact by the impacting arm 560. In a typical operation the inlet 520 valve will first be opened to allow metered flow of aerosol into the metering chamber 512. The outlet 530 valve is then opened to allow for dispensing of the aerosol. It will be appreciated that the illustrated pivotal mounting 564 of the impacting arm 560 only allows for impaction of one of the transfer pins 550, 552, and hence opening of only one of the inlet 520 or outlet 530 valves, at a time.

Figure 7 shows a simplified, schematic representation of a poppet valve actuation mechanism suitable for use in an aerosol metering valve herein. The metering valve might, for example be of a type similar to those shown in Figures 1 to 6 but including the poppet valve actuation mechanism now described. The portion of the valve body 610 which defines a metering chamber 612 is shown. The metering chamber has an outlet 630 permitting dispensing of aerosol from the metering chamber 612. The outlet 630 is provided with valve means comprising a valve poppet in the form of a resilient ball 634 biased into contact with a valve seat 632 by action of spring 636. An actuator rod 642 sits within and on both sides of an access hole 618 provided in the metering chamber 612. The tail end of the actuator rod 642 contacts the resilient ball 634 of the outlet 630 valve. The shaft of the actuator rod is housed within torque tube 652 and a handle 656 is provided to the head of the actuator rod.

Actuation of the valve of Figure 7 is achievable by rotating the actuator rod 642 such that its tail end physically dislodges the resilient ball 634 from its seat 622. The actuator rod 642 is rotated by use of the handle 656 at its head.

5 Figures 8a to 8d show various forms of poppet valve suitable for use in accord with the invention. These employ valve poppets having different forms. These alternative valve poppets may be used in the metering valves of Figs 1 to 6 or the poppet valve actuation mechanism of Figure 7 instead of the ball valve poppets shown therein.

10 In more detail, Figures 8a to 8d show a valve body 710a-d supporting a valve seat 732a-d and a valve poppet 734a-d which sits on valve seat 732a-d. In Figure 8a the valve poppet 734a is in the form of a mushroom. In Figure 8b the valve poppet 734b is in the form of a cone. In Figure 8c the valve poppet 734c is in the form of a disc. In Figure 8d the valve poppet 734d is in the form of a plug.

The aerosol container and valve of the invention is suitable for dispensing medicament, particularly for the treatment of respiratory disorders. Appropriate medicaments may thus be selected from, for example, analgesics, e.g., codeine, 20 dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate, ketotifen or nedocromil; antiinfectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti-inflammatories, e.g., beclomethasone dipropionate, fluticasone propionate, 25 flunisolide, budesonide, rofleponide, mometasone furoate or triamcinolone acetonide; antitussives, e.g., noscapine; bronchodilators, e.g., albuterol, salmeterol, ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, reproterol, rimiterol, terbutaline, isoetharine, tulobuterol, or (-)-4-amino-3,5-dichloro- α -[[[6- 30 [2-(2-pyridinyl)ethoxy] hexyl]methyl] benzenemethanol; diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium, tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon. It will be clear to a person 35 skilled in the art that, where appropriate, the medicaments may be used in the

form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament.

- 5 Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

- 10 Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) in combination with an antiinflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate).

- 15 It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

- 20 The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more of the following claims:

Claims

1. Metering valve for an aerosol container comprising

a valve body defining a metering chamber;

said metering chamber having an inlet and an outlet, said inlet permitting flow of aerosol from said container to the metering chamber and said outlet permitting dispensing of aerosol from the metering chamber;

the inlet having an inlet valve reversibly actuatable from an open to a closed position; and

the outlet having an outlet valve reversibly actuatable from a dispensing to a non-dispensing position, wherein said outlet valve comprises a outlet valve seat and an outlet valve poppet in biasable contact therewith.

2. Metering valve according to claim 1, wherein said inlet valve comprises an inlet valve seat and an inlet valve poppet in biasable contact therewith.

3. Metering valve according to either of claims 1 or 2, additionally comprising an outlet valve mover for moving the outlet valve poppet out of contact with the outlet valve seat.

4. Metering valve according to either of claims 2 or 3, additionally comprising an inlet valve mover for moving the inlet valve poppet out of contact with the inlet valve seat.

5. Metering valve according to either of claims 3 or 4, wherein either or both of said inlet valve mover or said outlet valve mover is mechanically actuatable.

6. Metering valve according to either of claims 3 or 4, wherein either or both of the inlet valve mover or the outlet valve mover is electrically actuable.

5 7. Metering valve according to claim 6, wherein either or both of the inlet valve mover or the outlet valve mover comprises a multi-component strip which is deformable in response to electrical current flow.

10 8. Metering valve according to claim 7, wherein said multi-component strip comprises multiple layers of different metals.

9. Metering valve according to claim 8, wherein said multi-component strip comprises a bimetallic strip.

15 10. Metering valve according to either of claims 7 or 8, wherein said multi-component strip comprises at least one piezoelectric material.

20 11. Metering valve according to either of claims 3 or 4, wherein either or both of the inlet valve mover or the outlet valve mover is magnetically actuable.

12. Metering valve according to claim 11, wherein either or both of the inlet valve mover or the outlet valve mover comprises magnetic material or material which is magnetically inductive.

25 13. Metering valve according to either of claims 3 or 4, wherein either or both of the inlet valve mover or the outlet valve mover is pneumatically actuable.

14. Metering valve according to either of claims 3 or 4, wherein either or both of the inlet valve mover or the outlet valve mover is hydraulically actuable.

30 15. Metering valve according to claim 14, wherein either or both of the inlet valve mover or the outlet valve mover comprises a fluid-filled bag or tube capable of transferring hydraulic force.

16. Metering valve according to any of claims 1 to 15, wherein the outlet valve poppet has a form selected from the group consisting of a ball, a mushroom, a cone, a disc and a plug.

5 17. Metering valve according to any of claims 2 to 16, wherein the inlet valve poppet has a form selected from the group consisting of a ball, a mushroom, a cone, a disc and a plug.

10 18. Metering valve according to any of claims 1 to 17, wherein said valve body additionally defines a sampling chamber and the inlet permits flow from the sampling chamber to the metering chamber.

15 19. Aerosol container comprising a metering valve according to any of claims 1 to 18.

20 20. Aerosol container according to claim 19, wherein the valve body of the metering valve is not movable relative to the container.

25 21. Aerosol container according to either of claims 19 or 20 comprising a suspension of a medicament in a propellant.

30 22. Aerosol container according to claim 21, wherein, said propellant comprises liquefied HFA134a, HFA-227 or carbon dioxide.

35 23. Aerosol container according to either of claims 21 or 22, wherein the medicament is selected from the group consisting of albuterol, salmeterol, fluticasone propionate, beclomethasone dipropionate, salts or solvates thereof and any mixtures thereof.

40 24. Aerosol container according to either of claims 19 or 20 comprising a compressed gas, preferably compressed air.

45 25. Inhalation device for dispensing medicament to a patient comprising a housing;

an aerosol container, locatable within said housing, said aerosol container comprising a metering valve according to any of claims 1 to 18; and

5 an outlet valve trigger for triggering the movement of the outlet valve poppet out of contact with the outlet valve seat.

10 26. Inhalation device according to claim 25, wherein the aerosol container comprises a metering valve according to any of claims 2 to 18, additionally comprising an inlet valve trigger for triggering the movement of the inlet valve poppet out of contact with the inlet valve seat.

15 27. Inhalation device according to either of claims 25 or 26, wherein either or both of said outlet valve trigger or said inlet valve trigger is triggerable in response to the breath of a patient.

20 28. Inhalation device according to claim 27, wherein either or both of the outlet valve trigger or the inlet valve trigger communicates with a sensor which senses the breath of a patient.

29. Inhalation device according to claim 28, wherein said sensor comprises an breath-movable element which is movable in response to the breath of a patient.

25 30. Inhalation device according to claim 29, wherein said breath-movable element is selected from the group consisting of a vane, a sail, a piston and an impeller.

30 31. Inhalation device according to claim 28, wherein said sensor comprises a pressure sensor for sensing the pressure profile associated with the breath of a patient.

35 32. Inhalation device according to claim 28, wherein said sensor comprises an airflow sensor for sensing the airflow profile associated with the breath of a patient.

33. Inhalation device according to claim 28, wherein said sensor comprises a temperature sensor for sensing the temperature profile associated with the breath of a patient.

5

34. Inhalation device according to claim 28, wherein said sensor comprises a moisture sensor for sensing the moisture profile associated with the breath of a patient.

10 35. Inhalation device according to claim 28, wherein said sensor comprises a gas sensor for sensing the oxygen or carbon dioxide profile associated with the breath of a patient.

15 36. Inhalation device according to claim 28, wherein said sensor comprises a piezoelectric element.

37. Inhalation device according to any of claims 25 to 36, wherein the outlet valve trigger and the inlet valve trigger are independently triggerable.

20 38. Inhalation device according to any of claims 25 to 36, wherein the outlet valve trigger and the inlet valve trigger are triggerable in a coupled fashion.

25 39. Inhalation device according to any of claims 25 to 38, wherein either or both of the outlet valve trigger or the inlet valve trigger is a mechanical trigger.

40. Inhalation device according to claim 39, wherein said mechanical trigger comprises a lever mechanism.

30 41. Inhalation device according to claim 39, wherein said mechanical trigger comprises a torque transfer mechanism.

35 42. Inhalation device according to any of claims 25 to 38, wherein either or both of the outlet valve trigger or the inlet valve trigger comprises a multi-component strip which is deformable in response to electrical current flow.

43. Inhalation device according to claim 42, wherein said multi-component strip comprises multiple layers of different metals.

5 44. Inhalation device according to claim 43, wherein said multi-component strip comprises a bimetallic strip.

45. Inhalation device according to either of claims 42 or 43, wherein said multi-component strip comprises at least one piezoelectric material.

10

46. Inhalation device according to any of claims 25 to 38, wherein either or both of the outlet valve trigger or the inlet valve trigger is a magnetic trigger.

15

47. Inhalation device according to claim 46, wherein the outlet valve trigger interacts magnetically with the outlet valve poppet and/or the inlet valve trigger interacts magnetically with the inlet valve poppet.

20

48. Inhalation device according to claim 46, wherein the outlet valve trigger interacts magnetically with a outlet shuttle contacting the outlet valve poppet and/ or the inlet valve trigger interacts magnetically with a inlet shuttle contacting the inlet valve poppet.

25

49. Inhalation device according to claim 48, wherein the outlet shuttle and/or inlet shuttle comprises magnetic material.

30

50. Inhalation device according to either of claims 48 or 49, wherein the outlet shuttle comprises material which is magnetically inductive and the outlet valve trigger comprises an inductive element capable of inducing magnetism therein and/or the inlet shuttle comprises material which is magnetically inductive and the inlet valve trigger comprises an inductive element capable of inducing magnetism therein.

35

51. Inhalation device according to any of claims 25 to 38, wherein either or both of the outlet valve trigger or the inlet valve trigger is a pneumatic trigger.

52. Inhalation device according to any of claims 25 to 38, wherein either or both of the outlet valve trigger or the inlet valve trigger is a hydraulic trigger.

53. Inhalation device according to claim 52, wherein the hydraulic trigger comprises a fluid-filled bag or tube capable of transferring hydraulic force.

10

15

Abstract

There is provided a metering valve for an aerosol container comprising a valve body defining a metering chamber; the metering chamber having an inlet and an outlet, the inlet permitting flow of aerosol from said container to the metering chamber and the outlet permitting dispensing of aerosol from the metering chamber; the inlet having an inlet valve reversibly actuatable from an open to a closed position; and the outlet having an outlet valve reversibly actuatable from a dispensing to a non-dispensing position, wherein the outlet valve comprises a outlet valve seat and an outlet valve poppet in biasable contact therewith.

THIS PAGE BLANK (USPTO)

1/8

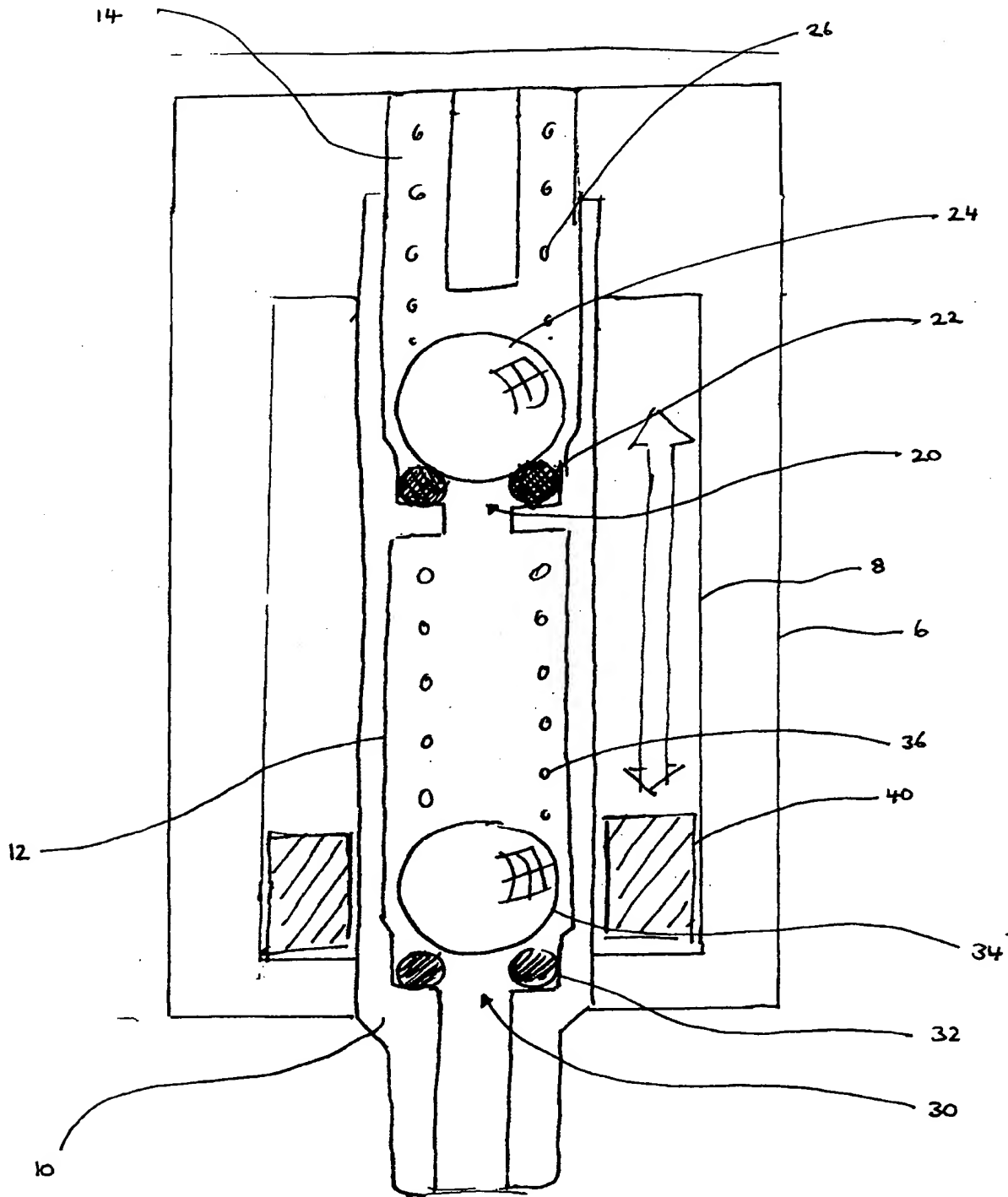


Fig. 1

THIS PAGE BLANK (USPTO)

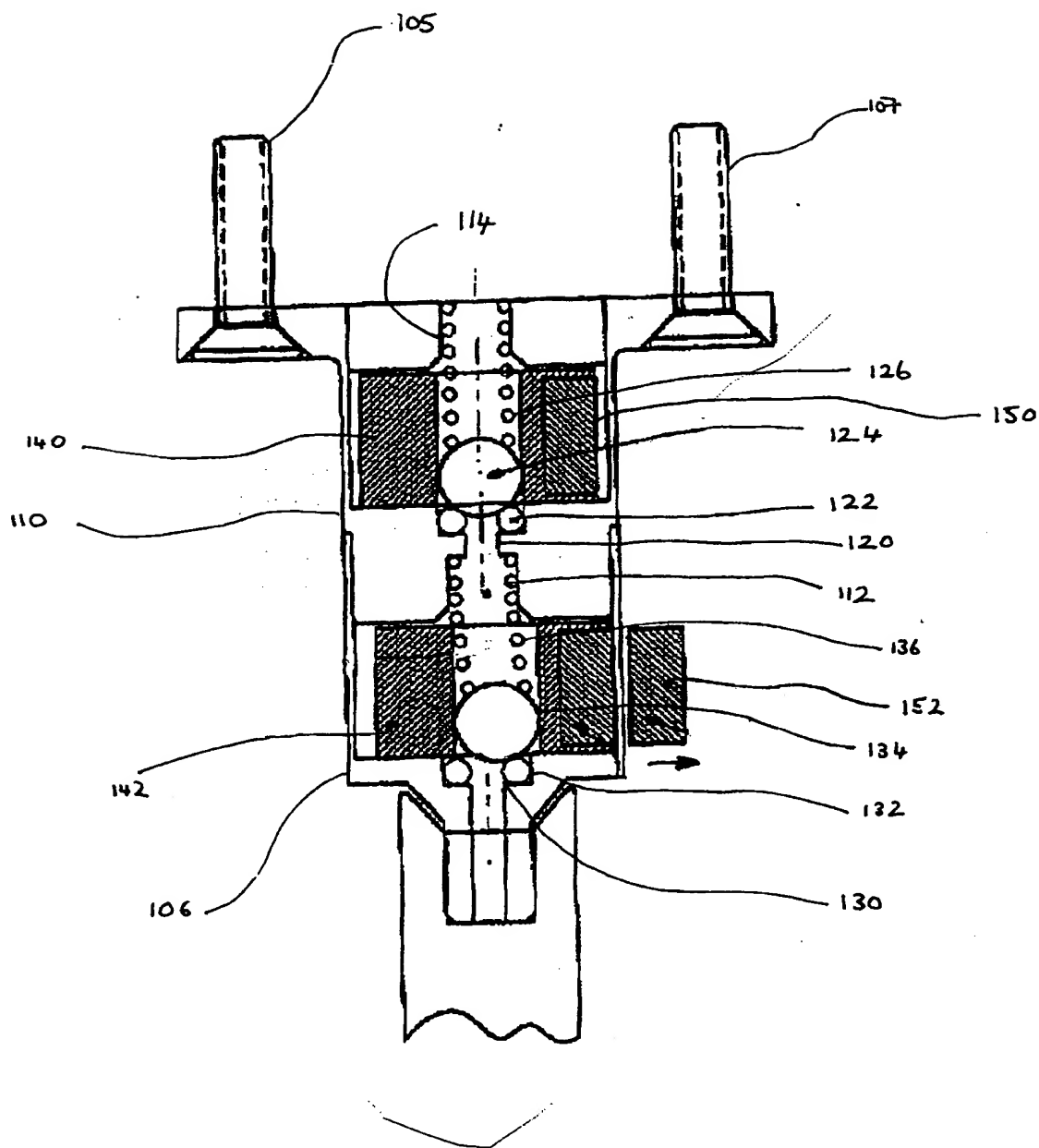


Fig. 2

THIS PAGE BLANK (USPTO)

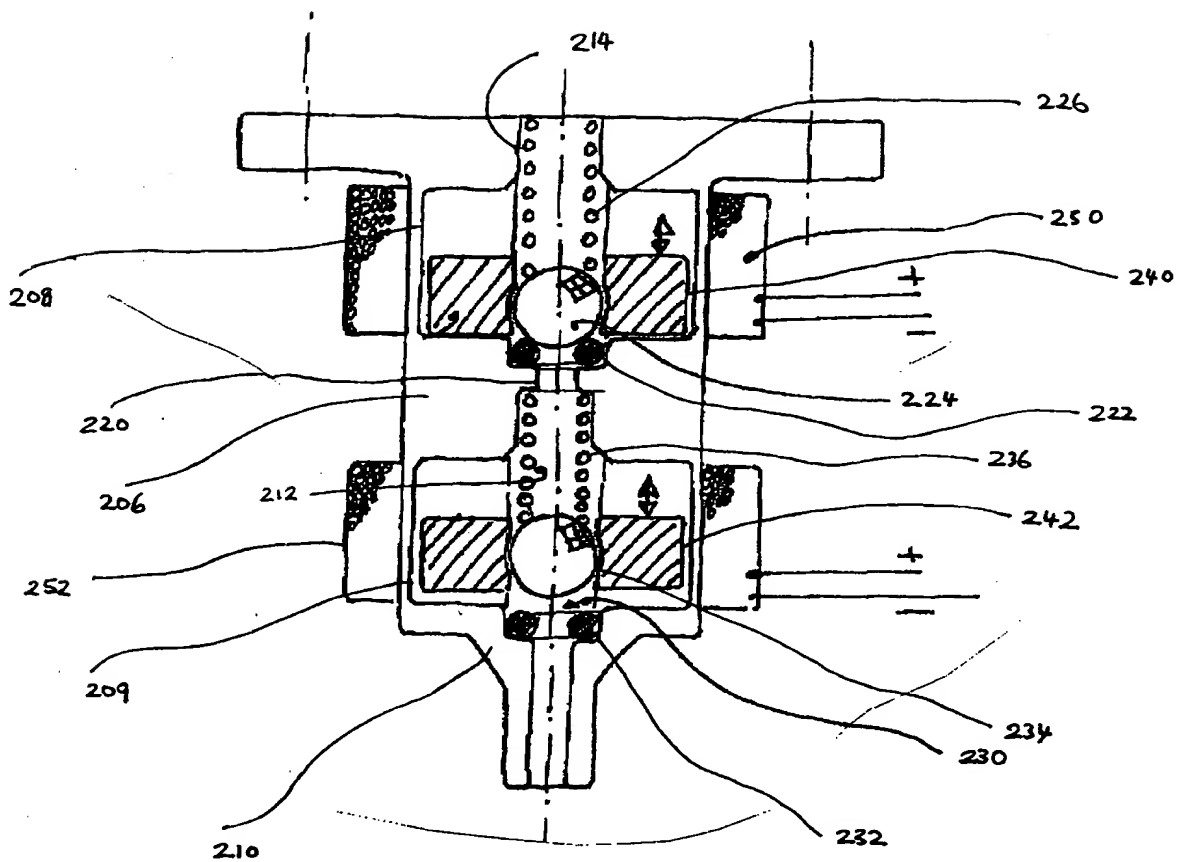


Fig. 3

THIS PAGE BLANK (USPTO)

4/8

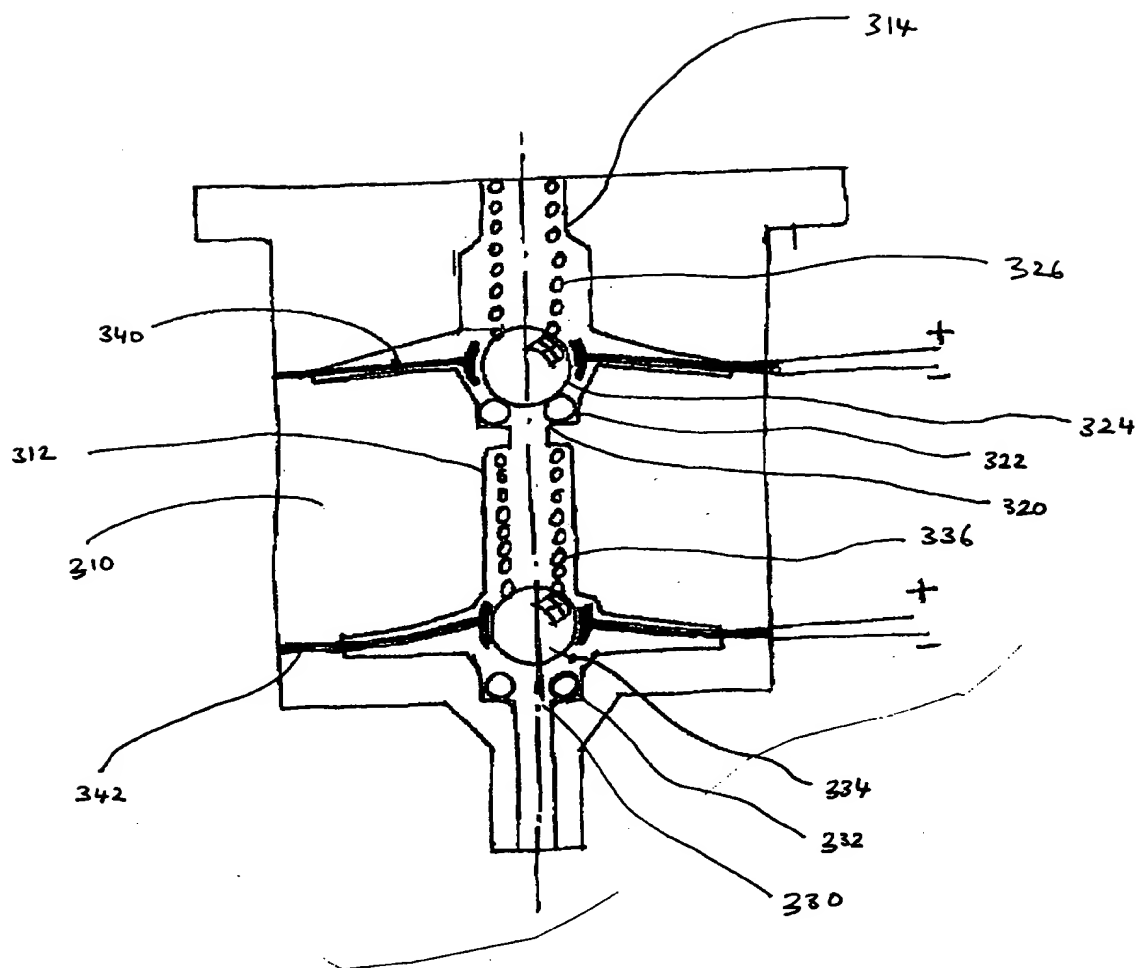


Fig. 4

THIS PAGE BLANK (USPTO)

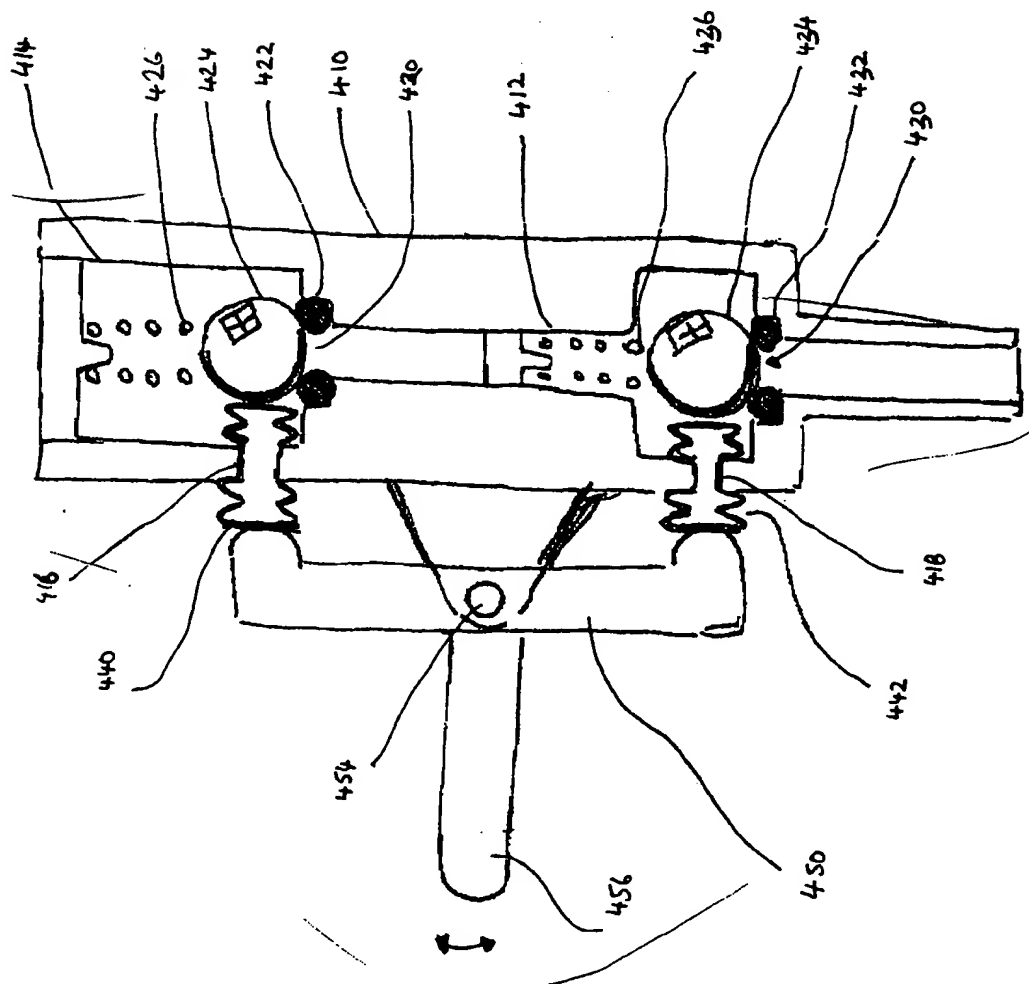


Fig. 5a

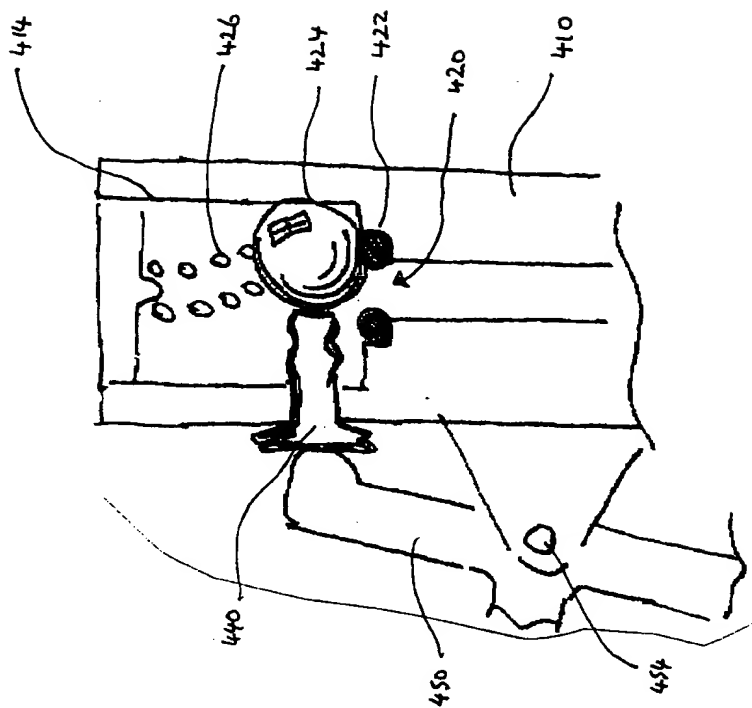


Fig. 5b

THIS PAGE BLANK (USPTO)

6/7

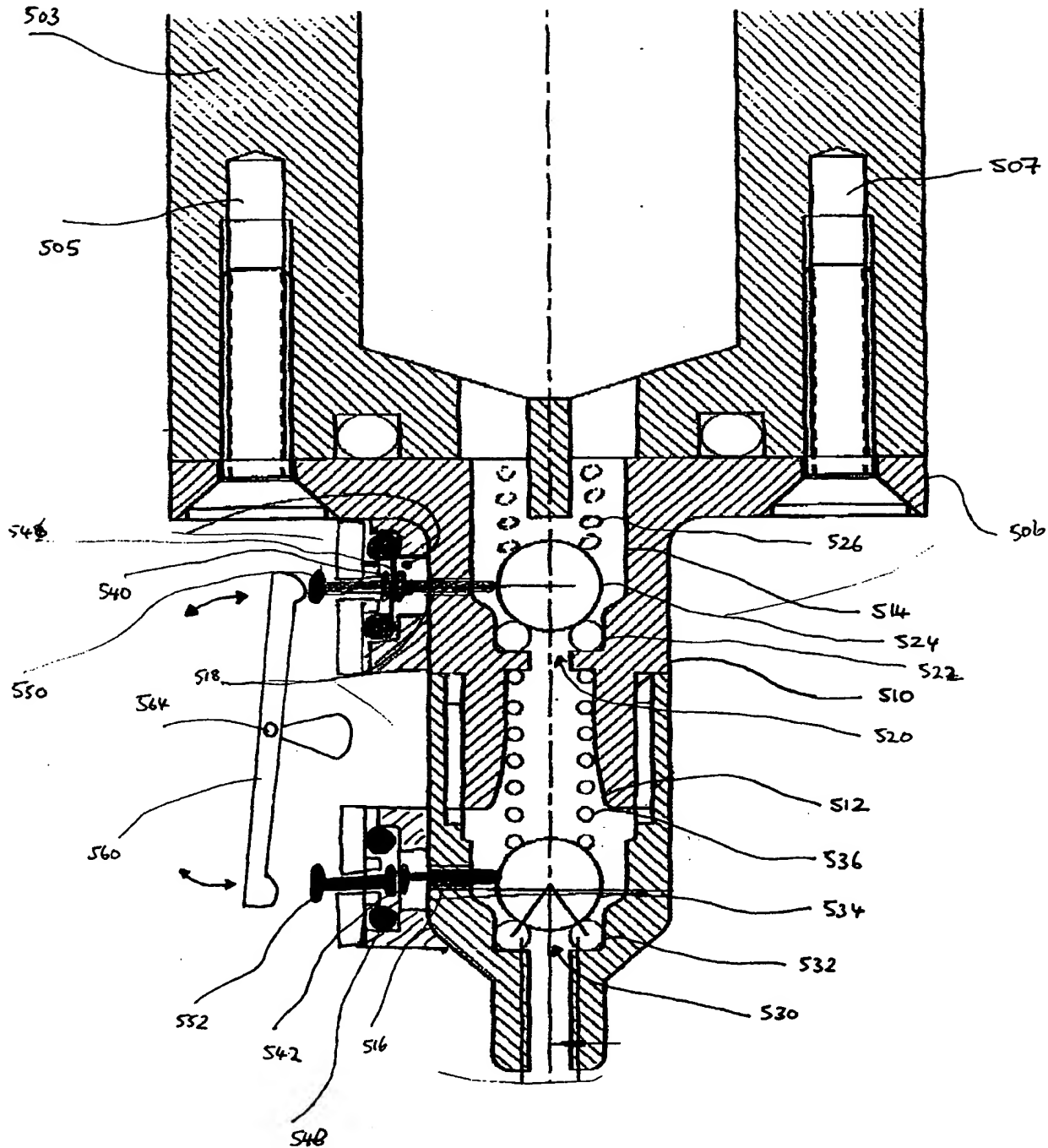


Fig 6.

THIS PAGE BLANK (USPTO)

7/8

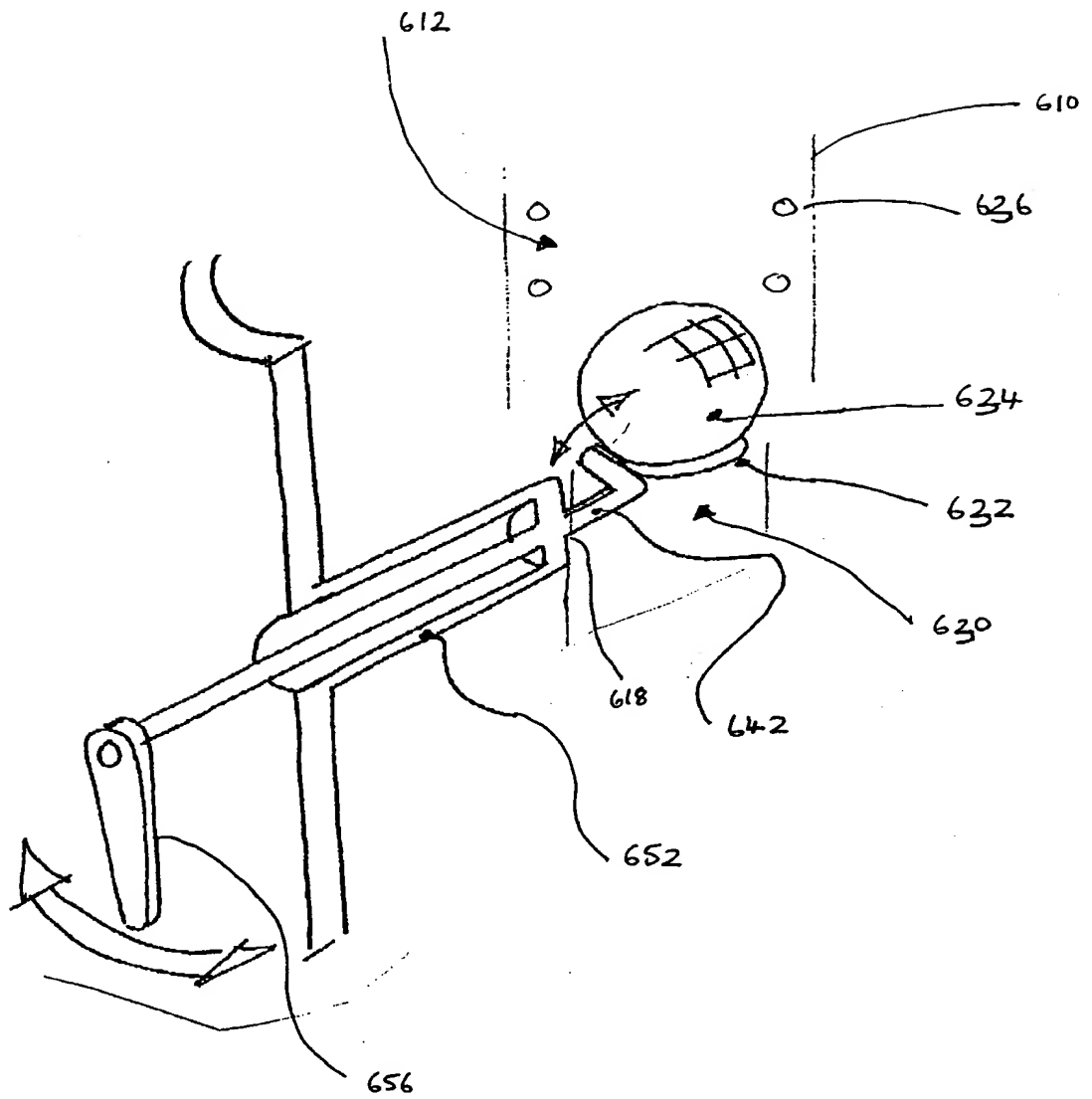


Fig. 7

THIS PAGE BLANK (USPTO)

Fig. 8a

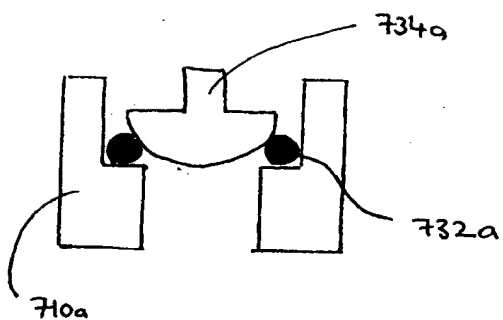


Fig. 8b

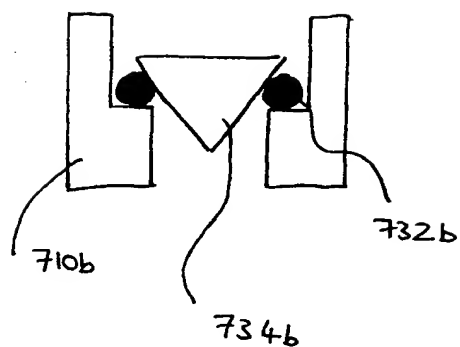


Fig. 8c

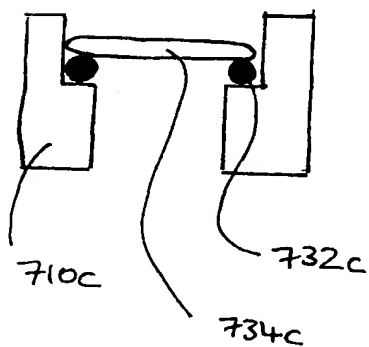
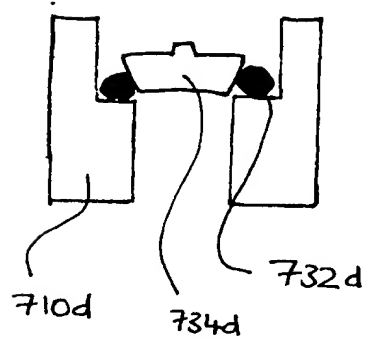


Fig. 8d



THIS PAGE BLANK (USPTO)